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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/442,111

11/17/1999

SHAWN DEFREES

14137-013820

5434

20350

7590

10/13/2006

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/442,111

Applicant(s)

DEFREES ET AL.

Examiner

Christian L. Fronda

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 53,55-58 and 60-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53,55-58 and 60-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Claims 53, 55-58, and 60-74 are pending and under consideration in this Office Action.

#### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 53, 55-58, and 60-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The arguments filed 05/02/2006 have been fully considered but are not persuasive. Applicants' position is that the novelty of the claimed methods is in the method steps and that accessory enzymes, glycosyltransferases, and product saccharides are adequately described in the specification. The examiner appreciates applicants' arguments but respectfully disagrees for reasons of record as stated below.

As stated in the previous Office Actions, genus claims 53, 55-58, and 60-74 encompass a genus of accessory enzymes, a genus of glycosyltransferases, and a genus of product saccharides, where the scope of the each genus includes many members from many biological sources with differing amino acid sequences and structures, and many product saccharides differing in structural, chemical, and physical characteristics.

The examiner maintains that the recitation of the names of the chemical compounds of each genus (e.g., accessory enzyme and glycosyltransferase) does not define any structural features commonly possessed by each claimed genus nor define any structural features commonly possessed by each claimed genus. Furthermore, the specification does not describe and define any structural features commonly possessed by each claimed genus.

The described transformed *E. coli* expressing a CMP-sialic acid synthetase/alpha 2,3-sialyltransferase fusion protein is used in the production of 3'-sialyllactose is not adequate to describe the full scope of the genus claims since the accessory enzymes and glycosyltransferases of the genus are expected to vary in amino acid sequence and structure, and there is no disclosure of a significant structural or functional element or property common to all members of the genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of each

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genus.

In view of these considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed genus of accessory enzymes, a genus of glycosyltransferases, and a genus of product saccharides.

Amending the claims to recite the specific accessory enzymes and their specific SEQ ID NO identifiers may overcome the rejection.

***Claim Rejections - 35 U.S.C. § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 53, 56-58, 60, 65-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samain et al. (Carbohydr Res. 1997 Jul 11;302(1-2):35-42; PTO 1449 filed 3/24/2003) in view of Ullrich et al. (J Bacteriol. 1995 Dec;177(23):6902-9). The teachings of the reference and the rejection of record have been stated in the previous Office Actions.

The arguments filed 05/02/2006 have been fully considered but are not persuasive for reasons of record as supplemented below. MPEP 706.02(j) states the following:

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In the rejection of record, the examiner has determined the scope and contents of the prior art, ascertained the differences between the prior art and the claims at issue, and found the claimed invention to have been obvious in light of the combined teachings of the references.

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One of ordinary skill in the art at the time the invention was made would have been motivated to combine the reference for the purposes of having an *E.coli* host cells that can overproduce UDP-GlcNAc which in turn can be used in the method of Samain et al. for making penta-N-acetyl-chitopentaose. One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success since transformation of *E.coli* host cells with heterologous nucleic acids are well known in the art. Thus, the claims are within the ordinary skill in the art to make and use at the time the invention was made, and was as a whole clearly *prima facie* obvious.

Amending the claims to recite the specific accessory enzymes and their specific SEQ ID NO identifiers may overcome the rejection.

6. Claims 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samain et al. in view of Ullrich et al. as applied to the claims above, and further in view of Bulow et al. (Trends Biotechnol. 1991 Jul;9(7):226-31). The teachings of the reference and the rejection of record have been stated in the previous Office Actions.

The arguments filed 05/02/2006 have been fully considered but are not persuasive for reasons of record and the reasons stated above as further explained below. In the rejection of record, the examiner has determined the scope and contents of the prior art, ascertained the differences between the prior art and the claims at issue, and found the claimed invention to have been obvious in light of the combined teachings of the references. The modified references teach the limitations of the invention, where the modified reference of Samin et al. encompasses cell based methods to make oligosaccharides and not proteins as asserted by applicants arguments. Thus, the claims are within the ordinary skill in the art to make and use at the time the invention was made, and was as a whole clearly *prima facie* obvious.

Amending the claims to recite the specific accessory enzymes and their specific SEQ ID NO identifiers may overcome the rejection.

### ***Conclusion***

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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